Deo Volente Orthopaedics

OCT 8 - 2004

K 042437

510(k) Summary of Safety and Effectiveness

SUMMARY PREPARED:	September 2, 2004
510(k) SPONSOR/APPLICANT:	Deo Volente Orthopaedics, LLC 345 N. Buffalo St., Warsaw IN 46580
510(k) PREPARER and CONTACT PERSON:	Dina L. Weissman, J.D. P.O. Box 83, Warsaw IN 46581 Tel/Fax: (574) 267-8828 Email: DLWeissman@aol.com
TRADE NAME:	Dorsal Intramedullary Plate
COMMON NAME:	Plate, Fixation, Bone
CLASSIFICATION:	Class II per 21 CFR § 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
DEVICE PRODUCT CODE:	87 HRS

PREDICATE DEVICES:

- Hand Innovations, Distal Radius Fracture Repair System, K032705, cleared 1 Oct 2003
- Wright Medical Technology, Locon-T Distal Radial Plate System, K994061, cleared 30 Nov 1999

DEVICE DESCRIPTION:

This anatomically contoured plate system offers several sizes and styles of distal heads in either titanium (ASTM F-136) or stainless steel (ASTM F-138).

The distal head of the plate contains two rows of two screw holes each that accept 2.7 mm screws. The distal row of screw holes are threaded allowing for fixed angle support of the fracture fragments utilizing the threaded head screws. The proximal row of screw holes has a spherical seat allowing for variability in screw angle fixation while still using the threaded head screws.

The threaded head screws vary in length from 16mm to 26mm and are fully threaded. K-wires may also be used for stabilization of bone fragments. The device utilizes a press fit intramedullary fixation for the proximal stem when inserted into the radial intramedullary canal while the distal head is secured to the fracture fragment using the above described bone screws.

INTENDED USE:

The fixation of fractures and osteotomies involving the distal radius. Single use device for cementless use only.

COMPARISON TO PREDICATES:

The Deo Volente Orthopaedics Dorsal Intramedullary Plate is similar to the listed predicate devices in intended use, performance characteristics, materials of construction, manufacturing methods and design.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

Deo Volente Orthopaedics, LLC
C/o Dina L. Weissman
P.O. Box 83
Warsaw, Indiana 46581

Re: K042437
Trade/Device Name: Dorsal Intramedullary Plate
Regulation Number: 21CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: September 2, 2004
Received: September 8, 2004

Dear Ms Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042437

Device Name: Dorsal Intramedullary Plate

Indications for Use:

The fixation of fractures and osteotomies involving the distal radius.

This single use device is for cementless use only.

Prescription Use XXXXX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K042437